IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA	**CRIMINAL NO. 16-** 795 (PG)
v.	**VIOLATION:**
ROSA BETANCOURT FARFAN	**Title 21, United States Code, §§ 331(k) and 333(a)(2).**

THE UNITED STATES ATTORNEY CHARGES:

At all times relevant to this Information:

Introductory Allegations

1. The Food and Drug Administration ("FDA") was an agency of the United States Government charged with the responsibility of protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), Title 21, United States Code, Sections 301-399f, to ensure that, among other things, medical devices sold for use by or upon humans were safe and effective, and bore labeling containing accurate information and adequate directions for use. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of devices introduced into interstate commerce.

2. The FDCA defined a " device" as, among other things, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the

body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." Title 21, United States Code, Section 321 (h)(2) and (3).

3. With certain exceptions not applicable here, under the FDCA, a Class III device was adulterated if it has not received FDA pre-market approval nor was it exempt from the requirement to obtain FDA pre-market approval. Title 21, United States Code, Section 351(f)(1)(B).

4. The FDCA prohibited the introduction or delivery for introduction into interstate commerce (or the causing thereof) of any device that was adulterated. Title 21, United States Code, Section 331(k).

5. The only injectable silicone products approved or cleared by FDA for marketing and use in the United States were ophthalmic devices for the treatment of eye injuries, such as detached retinas. These products were regulated by FDA as prescription medical devices. 21 C.F.R. § 886.4275. The FDA has not approved or cleared any liquid silicone devices for use in augmenting tissues, such as the buttocks or breasts.

COUNT ONE
Adulterating a Device
(Title 21, United States Code, Sections 331(k) and 333(a)(2))

Paragraphs One (1) through Five (5) of this Information are hereby realleged and incorporated as though fully set forth herein.

From in or about the year 2012 to in or about the year 2013, in the District of Puerto Rico and elsewhere within the jurisdiction of this Court,

ROSA BETANCOURT FARFAN,

the defendant herein, did acts to a device, that is, the injection of the device into a human body, the device being namely polydimethylsiloxane fluid, a/k/a, liquid silicone, after shipment of the device

and/or its components in interstate commerce and while the device was held for sale, which resulted in the device being adulterated within the meaning of Title 21, United States Code, Section 351(f)(1)(B), in that it was a Class III device that had not received FDA pre-market approval nor was it exempt from the requirement to obtain FDA pre-market approval.

All in violation of Title 21, United States Code, Sections 331(k) and 333(a)(2).

ROSA EMILIA RODRIGUEZ-VELEZ
United States Attorney

Jose Capo Iriarte
Assistant United States Attorney
Chief, Criminal Division

Myriam Fernandez Gonzalez
Assistant United States Attorney
Chief, Financial Fraud and Corruption Unit